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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,792	12/20/2001	John R. Adler	1010497-991130	2683

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,792

Applicant(s)

ADLER, JOHN R.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/07/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed on 2/15/2006 and they are not persuasive to the extend that the "stereotaxic radiosurgery" was not addressed . Therefore, as the limitation constitutes new grounds for rejection, this action is made Final.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweikard et al.'875 (US Patent No. 6,144,875).

Regarding claims 30-31, Schweikard et al.'875 teach depositing a fiducial into a target region of a patient (see col. 5, lines 31-33; referring to internal markers 152), detecting the fiducial using electromagnetic radiation to locate the target region of the patient (see col. 5, lines 33-46; referring to x-ray localization of the target region), and performing stereotaxic radiosurgery on the target region of the patient according to the detected fiducial and the location of the target region (see col. 3, lines 26-29).

Regarding claim 31, Schweikard et al.'875 further teach tracking the target region during the stereotaxic radiosurgery (see col. 3, line 39-col. 4, line 53; referring to tracking the target region while performing radiosurgery).

Regarding claim 32, Schweikard et al.'875 further teach applying radiation treatment to

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the target region (see col. 4, lines 9-22).

Regarding claim 33, Schweikard et al.'875 further teach anchoring the fiducial in the target region to prevent migration of the fiducial relative to the target region (see col. 5, lines 8-30; referring to the attachment of the fiducials or markers on the organ of interest so that organ can be traced for accurate treatment). Regarding claims 34-35, Schweikard et al.'875 further teach viewing the fiducial using an x-ray imager, wherein the fiducial comprises a radiopaque material or viewing the fiducial using an ultrasonic imager, wherein the fiducial comprises an ultrasonic opaque material (see col. 5, lines 20-30).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 36 is rejected under 35 U.S.C. 102(e) as being anticipated by Sirimanne et al.'904 of record.

Sirimanne et al.'904 teach a fiducial apparatus, comprising: a body portion having a housing (col. 12, lines 56-59, referring to the housing 400), the body portion being capable of being detected by electromagnetic radiation, and an anchor member coupled to the body portion, the anchor member (marker 402 is the anchor member in Figure 4A which is coupled to the body 400) having an unanchored position and an anchored position, the anchor member drawn into the housing in the unanchored position and withdrawn from the housing in the anchored position

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(see progressive figures 4A-4C wherein the marker 402 goes from the unanchored position in Figure 4A in the body 400 to the anchored position in Figure 4C wherein the marker is fully expanded in the cavity and hence anchored in the area of interest).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 37-41, 44-49, and 51-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al.'904 in view of Foester et al.'304.

Sirimanne et al.'904 teaches a fiducial apparatus to be inserted into a target region, comprising:

a body portion made of a material that is visible using electromagnetic radiation, including radioopaque or echogenic (col. 2, lines 54-60); and one or more anchoring devices connected to the body portion (col. 5, lines 4-11), each anchoring device having an unanchored position and an anchored position (col. 13, lines 54-62), the unanchored position permitting the body portion to move within the target region and the anchored position anchoring the fiducial apparatus into the target region (col. 13, lines 63-67 and col. 14, lines 1-6).

Sirimanne et al.'904 teach the body portion comprising a memory metal member that bends in response to an appropriate signal to anchor itself into the target region (see col. 13, lines 57-62).

Sirimanne et al.'904 teach the target region comprising a target region within a human body such as a tumor (see col. 1, lines 20-58).

Sirimanne et al.'904 teach the insertion further comprising injecting the fiducial into the target region using a needle (see device 400 in Figures 4A-4C).

Sirimanne et al.'904 teach wherein the anchor member is an elongated rectangular shaped member that embeds into the target region (see Figure 1C).

Sirimanne et al.'904 do not explicitly teach an anchoring device further comprising an anchor member and an elastic member connected to the anchor member that urges the anchor member into the anchored position or application of the anchoring device in non-void tissue.

In the same field of endeavor, Foester et al.'304 teach a spring structure (or an elastic member) connected to the anchor member that urges the anchor member into the anchored position (see paragraph 0019) wherein the anchor member can thereby be attached to non-void tissue.

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al.'904 and incorporated the teachings of Foester et al.'304 of incorporating a spring structure as that enhances the implantation of the marker (as explained by Foester et al.'304 in paragraph 0019) in tissue such as non-void tissue.

Foester et al.'304 teach an anchor member comprising a spike that embeds itself into the target region or a pyramidal shaped member (see Figures 17, showing multiple spikes or multiple pyramidal members).

It would have been obvious to one skilled in the art at the time that the invention was made to have moved one or more anchor devices into an anchored position in order to embed the

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one or more anchor devices into the target region, depending on the size of the target of interest, requiring more marking identification, as this is a well known practice to those skilled in the art.

Please note that “stereotactic surgery” which means nothing more than tracking the internal area of interest which was already addressed.

7. Claims 42-43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al.’904 in view of Foester et al.’304 and further in view of Flomenblit et al.’641.

Sirimanne et al.’904 do not explicitly teach that an appropriate signal further comprises an electric field or a predetermined temperature.

In the same field of endeavor, Flomenblit et al.’641 teach the use of an appropriate signal further comprising a predetermined temperature to insert a coiled structure into the area of interest (see col. 2, lines 61-67 and col. 3, lines 1-64). Note that an electric field is required to change the temperature since an electronic apparatus is used.

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al.’904 and incorporated the teachings of Flomenblit et al.’641 in order to introduce the coiled marker (such as the one indicated in Figure 5D of Sirimanne et al.’904) into the area of interest.

Sirimanne et al.’904 teach the memory metal further comprising nitinol (see col. 13, lines 54-62).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

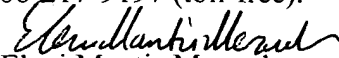
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM